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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/813,980 | 03/31/2004 | Edward Wells Knowlton | 1000 -010 | 5920 |
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| HELLER EHRMAN LLP 4350 La Jolla Village Drive, 7th Floor San Diego, CA 92122 | | | EXAMINER SWEET, THOMAS | |
| | | | ART UNIT 3774 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/813,980

Applicant(s)

KNOWLTON, EDWARD WELLS

Examiner

Thomas J. Sweet

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 8 of the remarks, filed 01/14/2008, with respect to the rejection under 35 USC 112 have been fully considered and are persuasive. The rejection of claims 1-30 under 35 USC 112 has been withdrawn.

Applicant's arguments, see page 8 of the remarks, filed 01/14/2008, with respect to the rejection under double patenting have been fully considered and are persuasive. The rejection of claims 1-3, 8, 10-22, 24-26 and 30 under double patenting has been withdrawn.

Applicant's arguments filed 01/14/2008 have been fully considered but they are not persuasive. Knowlton clearly include pre-positioning for example in the background of the invention liposuction is use prior to the treatment which constitutes pre-positioning. Additionally, it is inherent to pre-positioning the patient so as to access the treatment area which also constitutes pre-positioning.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 14-24, 26-29, 31-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Knowlton (US 6,350,276). Knowlton discloses a method of energetically treating a target tissue site (col 11-12, thermal), the method comprising: pre-positioning tissue in a aesthetically (background on the invention, such as line 40-42 and inherent positioning of the

patient for access) correct configuration (cols 19-20, lines 62-3, contact and pressure are required otherwise there is no current flow) delivering energy to the tissue site using an energy delivery device (col 12, lines 5-11); delivering a vectored mechanical force to the tissue site (col 12, lines 5-11); producing a thermal adhesion or lesion at the tissue site (i.e. cleave of collagen crosslinks); and remodeling at least a portion of tissue at the tissue site (to achieve a smoother contour).

With regard to claims 2 and 3, inherently a patient is pre-positioned for treatment (e.g. a patient is placed on an operating table, standing, etc...) in conjunction with the treatment.

With regard to claims 22, 33, 37 and 39, selecting the tissue site based on an amount of convexity at the tissue site (inherent to smooth the contour).

With regard to claims 4-7, 31, 35-36 and 38, producing a plurality of adhesions or lesions is substantially continuous or at least partially overlapping and delivering energy in a selected pattern (Col 6, lines 5-48, discontinuous modes/pattern of application, specifically lines 22-23 states power is pulsed which is overlapping and a pattern).

With regard to claim 8, the force is a substantially uniform force applied over the tissue site (col 12, line 17).

With regard to claims 9-10, force profile with respect to a radial direction of a force application surface, the force profile substantially increasing in an inward direction with respect to an edge of the force application surface (col 17, lines 8-22- the tissue interface inherently applies this force profile by having radiused edges and as described in the paragraph from col 18-19)

With regard to claim 11, delivering a first force in a first direction and delivering a second force in a second direction (col 12, lines 17-24).

With regard to claim 14, pre-positioning tissue at the tissue site substantially prior to energy delivery to shape the tissue adhesion or lesion or create a directed wound healing response (the disclosed bipolar RF energy system requires contact with the skin to work and the tensioning device 16 is separate from the electrodes 18 which pre-contact the tissue as the electrode are brought into contact with the tissue).

With regard to claims 15-16, 19, 34 and 38, cooling a layer of tissue or a surface layer of tissue of at least a portion of the tissue site (col 4, lines 7-9) and producing a reverse thermal gradient within at least a portion of the tissue site (col 5, lines 52-59) which preserves at least a portion of a surface, a tissue layer or an epidermal layer at or adjacent the tissue site.

With regard to claims 27 and 29, performing a liposuction procedure substantially at the tissue site (col 1-2, lines 54-16).

With regard to claim 28, skeletonizing at least a portion of fibrous septae at the tissue site (an unintended side effect as discussed in Col 12 lines 34-49).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 13, 25 and 30 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Knowlton. Knowlton discloses a method of energetically treating a target tissue site as discussed above including a positive force (positive pressure, greater than zero). Knowlton anticipated and clearly envisaged the range (range of .01-10 ... 2.5-10 lbs) by having a range (greater than zero) overlapping the claimed ranges. It this does not establish sufficient specificity. Applicant has not disclosed that having force in the claimed ranges solves any stated problem or is for any particular purpose. Moreover, it appears that the method would perform equally well with any positive force up to the point of tissue destruction. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the range of 2.5-10 lbs because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Knowlton.

Conclusion

This is a RCE of applicant's earlier Application No. 10/813980. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas J Sweet/
Primary Examiner, Art Unit 3774